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ATTORNEY DOCKET NO. 21108.0040U1  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of	)	
	)	
Kyrkanides	)	Art Unit: 1632
	)	
Application No. 10/781,142	)	Examiner: Joanne Hama, Ph.D.
	)	
Filing Date: February 18, 2004	)	Confirmation No. 3987
	)	
For: "VECTORS HAVING BOTH ISOFORMS	)	
OF BETA-HEXOSAMINIDASE AND	)	
USES OF THE SAME"	)	

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. § 1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(c), in that neither a final Office Action nor a Notice of Allowance has been mailed to Applicants. Accordingly, Applicants make the statement required under 37 C.F.R. § 1.97(c)(1).



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The undersigned hereby certifies that each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

No fee is believed due; however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-145. on the date indicated below.

P. Brian Giles

3/30/06  
Date



**INFORMATION DISCLOSURE  
STATEMENT LIST**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,142
Filing Date	February 18, 2004
First Named Inventor	Kyrkanides
Group Art Unit	1632
Examiner Name	Joanne Hama, Ph.D.

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Document No.	Date	Name	Class	Subclass	Filing Date (if appropriate)

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document Country Code-Number- Kind Code	Date	Name	Translation Yes/No
	B1	WO 02/44355	June 6, 2002	Vaccaro et al.	

**NON-PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	B2	Arfi, et al., "Bicistronic lentiviral vector corrects beta- hexosaminidase deficiency in transduced and cross-corrected human Sandhoff fibroblasts," Neurobiology of Disease, Vol. 20, 2:583-593, 2005
	B3	Bourgoin, C., et al., "Widespread distribution of beta-hexosaminidase activity in the brain of a Sandhoff mouse model after co-injection of adenoviral vector and mannitol," Gene Therapy, Vol. 10, 21:1841-1849, 2003
	B4	Guidotti, J., et al., "Retrovirus-mediated enzymatic correction of Tay-Sachs defect in transduced and non-transduced cells," Human Molecular Genetics, Vol. 7, 5:831-838, 1998
	B5	Guidotti, J., et al., "Adenoviral gene therapy of the Tay-Sachs disease in hexosaminidase a-deficient knock-out mice," Human Molecular Genetics, Oxford University Press, Vol. 8, 5:831-838, 1999
	B6	Havenga, M., et al., "Second gene expression in bicistronic constructs using short synthetic intercistrons and viral IRES sequences," Gene Vol. 222:319-327, 1998
	B7	Kyrkanides, S., et al., "Transcriptional and posttranslational regulation of cre-recombinase by RU486 as the basis for an enhanced inducible expressions system," Molecular Therapy: The Journal of the American Society of Gene Therapy, Vol. 8, 5:790-795, 2003
	B8	Kyrkanides, S., et al., "Beta-hexosaminidase lentiviral vectors: transfer into the CNS via systemic administration", Molecular Brain Research, Elsevier Science, Vol. 133, 2:286-298, 2005
	B9	Lacorazza, H., et al., "Expression of human beta-hexosaminidase alpha-subunit gene (the gene defect of Tay-Sachs disease) in mouse brains upon engraftment of transduced progenitor cells," Nature Medicine, Vol. 2, 4:424-429, 1996
	B10	Poeschla, E., et al., "Efficient transduction of non-dividing human cells by feline immunodeficiency virus lentiviral vectors" Nature Medicine, Vol. 4, 3:354-357, 1998
	B11	Teixeira, C., et al., "Retrovirus-mediated transfer and expression of beta-hexosaminidase alpha-chain cDNA in human fibroblasts from GM2-gangliosidosis B1 variant," Human Gene Therapy, Vol 12, 14:1771-1783, 2001
	B12	Wildner, et al., "Generation of a conditional neo(r)-containing retroviral producer cell line: effects of neo(r) on retroviral titer and transgene expression," Gene Therapy, Vol. 5, 5:684-691, 1998

Examiner Signature:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.